

Application No. 09/729,888  
Amendment Dated October 27, 2003  
Reply to Office Action of May 7, 2003

**REMARKS/ARGUMENTS**

By this Amendment, claims 15, 16 and 18 are canceled and claims 9 and 12 are amended.  
Claims 9 - 14 are pending.

The Examiner sets forth that Zinreich discloses in Figures 1-5d a pre-surgical alerting device comprising a strip (according to the Examiner the strip is made up of the markers shown in Fig. 5b), a visually perceivable indicator (16, 18 and 20), a temporary attachment means (Col. 3, lines 33-36), the strip is perforated (Col. 3, lines 29-31), a peelable packing (12, 14a and 14b), a companion label 22, a method of attaching the strip to the body as recited in Claim 15, a notification strip (the markers shown in Fig. 5b), visually perceivable indicators (16 and 20), a temporary attachment means (Col. 3, lines 33-36), a warning strip (1 of 18), visually perceivable indicator (the remain sets of 18) and temporary attachment means (the adhesive as set forth above) as recited in Claim 16.

The Examiner further sets forth that Zinreich discloses in Figs. 1-5d a pre-surgical alerting device, substantially as claimed. However, the Examiner believes that Zinreich does not disclose using the words "NO CUT." According to the Examiner, Keeton teaches in Figures 1-3 using words to indicate what should or should not (the Examiner is interpreting that if a medical attendant indicates what to operate on that person is also indicating what not to operate on) be operated on. The Examiner believes that it would have been obvious to one having ordinary skill in the art at the time that the invention was made that the words "NO CUT" or any other words as taught by Keeton could be substituted for one of the markers as disclosed by Zinreich in order to indicate an area that the surgeon should not operate on.

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The Examiner also sets forth that Keeton teaches in Figures 3-4 a pre-surgical alerting method comprising applying a skin penetrating applique of a message warning against surgery to a body segment (using the label 42). According to the Examiner, the label has a pressure sensitive label that is covered by a backing. The Examiner notes that the Examiner is interpreting the pressure sensitive label as an adhesive. However, if the Applicant disagrees, the Examiner believes that De Woskin teaches in Figures 1-3 an identification band comprising an adhesive according to the Examiner. Additionally, the Examiner believes that Zinreich also teaches an adhesive (as set forth above). The Examiner believes that it would have been obvious to one having ordinary skill in the art at the time the invention was made that the adhesive as taught by De Woskin and Zinreich could be substituted for the pressure sensitive material as disclosed by Keeton because either attachment means could be used to attach the label to the patient. The Examiner is interpreting that the adhesive will penetrate the user's skin.

Keeton teaches surgical clothing and labeling means for protection of a patient entering surgery. The system taught by Keeton includes both a gown and labels. The gown is made of a disposable material so that the gown as a whole can remain in place on the patient while portions thereof are cut away to allow required access to the body. The labels taught by Keeton designate an area of an intended surgical operation.

Zinreich teaches radiation therapy skin markers which are used to delineate a radiation therapy portal area on a patient's skin surface. The markers taught by Zinreich geometrically define the area to be radiated by delineating corners, and defining isocenters, geometries, set-up point

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markers, lengths and intersections of the area to be radiated. Thus, the markers taught by Zinreich designate an area of an intended procedure.

Conversely, the Applicant's invention is a device for selecting an unintended body segment and indicating that the unintended body segment is not to be involved in a surgical procedure. Therefore, the Applicant's amended Claim 9 sets forth a pre-surgical alerting device for use on a body having an involved body segment to be involved in a surgical procedure and a plurality of uninvolved body segments which are not to be involved in the surgical procedure. Claim 9 also recites a body segment selected from the plurality of uninvolved body segments to provide a selected uninvolved body segment and a strip suitable for placing on the selected uninvolved body segment to provide a labeled selected uninvolved body segment. The strip has a superior side and an inferior side. A visually perceivable indicator is provided on the superior side to warn against surgery on the labeled selected uninvolved body segment. The alerting device of Claim 9 also includes temporary attachment means for temporarily attaching the inferior side to the labeled uninvolved body segment in a manner which permits the strip to be removed after the surgical procedure.

Keeton does not provide a visually perceivable indicator to warn against surgery on a labeled selected uninvolved body segment. Keeton teaches labeling the involved body segment rather than the uninvolved body segment.

However, the Examiner appears to believe that the system taught by Keeton may indicate uninvolved body segments by virtue of the fact that it indicates the involved body segment. In this

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interpretation, the body segments that are not labeled are apparently thereby indicated as not involved by virtue of the fact that they are not indicated as involved.

To the extent that this may be true, it is still clear that Keeton does not teach labeling a selected uninvolved body segment and thereby providing a labeled selected uninvolved body segment. There is an important distinction between: i) indicating all of the unlabeled body segments that are not involved (as taught by Keeton), and ii) indicating that a selected body segment is not involved (as claimed by Applicant) and specifically labeling the selected body segment. The Applicant's alerting device singles out a selected body segment to be labeled, wherein the body segment thus selected is the one which may be the most likely to be mistakenly operated upon.

For example, if a left eye is to be operated on, the right eye may be the most likely uninvolved body segment to be accidentally operated upon. Thus, the right eye is the selected body segment which is labeled in the Applicant's system. By labeling the right eye in this manner, the Applicant's invention prevents the most likely mistake from occurring.

Therefore, Keeton and Zinreich do not provide a visually perceivable indicator to warn against surgery on the labeled selected uninvolved body segment as required by amended Claim 9. These references teach labeling the involved body segment, rather than the uninvolved body segment. To the extent that the systems taught by these references indicate uninvolved body segments by virtue of the fact that they indicate the involved body segment, they still do not teach labeling a selected uninvolved body segment, as previously described in more detail above. This is

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an important distinction wherein the uninvolved the body segment which is most likely to be mistakenly operated upon is labeled in the Applicant's system.

Furthermore, Keeton and Zinreich cannot be legitimately combined in an attempt to render the Applicant's invention obvious. Zinreich is inherently limited to providing markers for procedures to be performed on involved body segments. The markers of Zinreich are in reality a plurality of markers acting cooperatively to geometrically define an area to be operated upon by delineating corners and defining isocenters, geometric, set-up point markers, etc. They have no meaning whatsoever in the context of defining an area not be operated upon, and are thus not analogous to the Applicant's field of art.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the

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application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

October 27, 2003

Please charge or credit our Account  
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entry and/or ensure consideration of  
this submission.

By Frank M. Linguiti  
Frank M. Linguiti  
Registration No. 32,424  
Customer No. 03000  
(215) 567-2010  
Attorneys for Applicant